

**REMARKS**

Applicant submits that the present amendment is fully responsive to the Office Action dated February 1, 2005 and, thus, the application is in condition for allowance.

By this reply, claims 24-28, 35, 36, 46 and 49 are canceled, claims 48 and 50 are amended, and claims 52-67 are newly added. Claims 29-34, 37-45 and 47 remain withdrawn from consideration at this time. Claims 48 and 50-67 remain pending. Of these, claims 48, 50, 52, 53, 58, 59 and 62 are independent. An expedited review and allowance of the application is respectfully requested.

Applicant's representative extends his sincere gratitude to Examiner Dawson for graciously agreeing to an interview at the USPTO scheduled on February 10, 2005. During such interview, Applicant's representative presented a description of a particular embodiment as shown in Figure 9a with support from the figures and the specification. Then the Office Action was discussed. Examiner agreed that upon receiving the present Amendment and determination of allowance of any claims, he will re-review the prior claims that were previously withdrawn from consideration and deem if any such claims should also be reconsidered. With respect to the objection to the specification, it was agreed that body of original claim 23 may be entered in paragraph form within the specification. With respect to the objection to the drawings, it was agreed that to resolve the lack of showing of a "handle" in the embodiment shown in Figure 9a, that a generic "black box" rendering of such a handle 45 may be entered within the drawing because such support has been provided in the specification as filed. The corresponding text in the specification relating to the drawing may also be changed to reflect the inclusion of generic handle 45. Finally, with respect to the claims, it was agreed that claim language that included some discussion of an elongated tubular structure having a grasping device at an end to hold

tissue would be sufficient to overcome the cited art of record. It is believed that the amendments and remarks presented herein are directly reflective of the discussion of the Interview and any and all of the issues of the outstanding Office Action have been resolved and, thus, an expedited allowance of the present invention is respectfully requested.

In the outstanding Office Action, claims 26, 27, 29-34, 37-45 and 47 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention or species. Furthermore, it was held that the term “straightening tube” was indicated in some of the claims that were deemed in the Office Action to not be part of the elected species. Some of the claims that were withdrawn have been canceled. To the extent that the remaining claims are still deemed as withdrawn, Applicant respectfully traverses.

The term “straightening tube” has been used to describe any housing that has an aperture, opening or lumen in which a needle is compressible within, and does not necessarily have to take on a shape of a traditional “tube,” *per se*. However, to expedite the prosecution of this application, an amendment has been made to change the term “straightening tube” to –elongate tubular member– or –elongate member– or the like to describe the embodiment being claimed in terms of a housing which may contain a needle or needle-like structure within. Applicant respectfully requests, upon allowance of independent claims, a re-review of the claims that are currently deemed as withdrawn to determine their patentability as is the duty according to MPEP § 803.

In the outstanding Office Action, the specification was objected to as failing to provide proper antecedent basis for the claimed subject matter, specifically for the elements described in claim 46 referring to the radius of curvature. Application respectfully traverses.

The original application did contain language to support the elements of claim 46. For example, original claim 23 contained nearly identical language to claim 46, and must be considered as a part of the original disclosure. To render this objection moot, Applicant is inserting the substantive language of originally filed claim 23 in paragraph form within the body of the specification, after paragraph 31 and before paragraph 32. Such paragraph amendment to the specification should be entered because the language contained therein is fully supported by the original specification, and for example, in original claim 23. Furthermore, to expedite the prosecution of this application, claim 46 has been canceled, further rendering the current objection moot. However, Applicant reserves the right to re-present this claim in subsequent prosecution, such as in continuations and/or divisional applications.

In the outstanding Office Action, the drawings were objected to as not having shown every feature of the invention specified in the claims. More particularly, a “handle” was not shown in the elected species shown in Figure 9a. At the Examiner Interview of 2/10/05, it was agreed that an amended drawing may be submitted that shows Figure 9a with a generic handle (as indicated by label 45) to allow for inclusion of the element of “handle” within the present claims. Such inclusion is not new matter as the language of paragraph 71 describing Figure 9a makes direct reference to a handle at a proximal side of the device. Acceptance of the drawing sheet including Figures 9a and 9b is respectfully requested. Such sheet is attached at the end of this Amendment and identified by the label “Replacement Sheet” in the page header.

In the outstanding Office Action, claims 24, 25, 28 and 49-51 were rejected under 35 U.S.C. § 102(b) as being anticipated by Middleman (U.S. Pat. No. 5,820,628). It is asserted that Middleman discloses a device having an outer tube (10) and an inner member (14), a proximal

handle (20) and a needle, among other alleged features. Thus, it is concluded that Middleman anticipates the present invention as recited in the claims. Applicant respectfully traverses.

Neither Middleman, nor any other related art of record, alone or in combination, disclose or fairly suggest the present invention as recited in the pending claims. Independent claims 48, 50, 52, 53, 58, 59 and 62 have been presented which clearly and fairly distinguish the present invention from that of the art of record. They have support in the original application and claims as filed and contain no new matter. To the extent that the prior rejection is deemed to be applicable to the newly presented and pending claims, they are respectfully traversed.

The present invention, as recited in the pending claims, discloses a device that includes an elongated or tubular structure having some type of lumen to be able to receive a needle or similar structure. Furthermore, a grasping mechanism is included or connected to the device such that the grasping mechanism maintains tissue in a relatively stable position while the needle pushes suture through the tissue. Such mechanism or ability is neither specifically disclosed nor fairly suggested by Middleman. Even if, *arguendo*, Middleman is able to advance suture with its device shown in Figure 7, it is not capable of maintaining soft tissue in a stable position while doing so. In fact, the devices shown by Middleman are not able to function in the way disclosed and claimed herein by both holding tissue and advancing suture therethrough. Thus, Middleman cannot render the present claims as anticipated or obvious. Furthermore, Middleman cannot be used in combination with any other related art of record to obviate the present invention as recited in the claims.

In the outstanding Office Action, claims 35, 36, and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Middleman. It is asserted that Middleman discloses the present invention as claimed with the exception of the specifically claimed radius of curvature,

and such radius would be deemed as an obvious design choice. Thus, the claims are unpatentable because they are obvious. Applicant respectfully traverses.

To expedite the prosecution of this patent application, the claims in question have been canceled and so the rejection is deemed moot. However, Applicant retains the right to pursue them in subsequent applications. To the extent that the rejection or line of argument is deemed applicable to the present claims or future claims, they are respectfully traversed.

Middleman shows figures that reflect a needle in a tube, with such needle curving in Figure 7. However, such figures are merely exemplary and cannot be used to reflect a 1:1 direct scale reflection of the actual mechanism and geometry of the devices disclosed. Middleman makes no mention that the embodiments shown by its figures are a direct geometric replica or scale model of the actual embodiments of his invention. Further, there is no mention of the importance of geometry in his description. Thus, because Middleman does not disclose any information as to geometry or scale in its drawings nor its text, it cannot be inferred from its exemplary drawings. Further, if such scaling or geometry was of value to Middleman, it surely would have been specifically disclosed. Thus, the conclusion that is gleaned is that Middleman did not appreciate and did not disclose or suggest the role of radius of curvature in the devices disclosed in its patent. Nonetheless, to expedite the prosecution of the present application, Applicant has removed language referring to scaling and geometry, but reserves the right to pursue such language in claims in subsequent applications or prosecution.

Applicant graciously acknowledges the allowance of claim 48 and proposes a minor amendment to it by adding the word “device” to clarify the preamble of the claim. The amendment is not substantive and claim should remain allowable.

By this amendment, claims 52-67 are newly added and read on the elected species shown in Figure 9a. Support for the new claims may be found in the specification and drawings as originally filed. Currently, claims 48 and 50-67 remain pending in this application.

If any fees are associated with the entering and consideration of this preliminary amendment, please charge such fees to our Deposit Account 50-2882.

As all of the outstanding rejections have been traversed and all of the claims are believed to be in condition for allowance, Applicant respectfully requests issuance of a Notice of Allowance. If the undersigned attorney can assist in any matters regarding examination of this application, Examiner is encouraged to call at the number listed below.

Respectfully submitted,

David DIDUCH et al.

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**IN THE DRAWINGS**

Please enter corrected drawing sheet attached herein and labeled "Replacement Sheet," showing Figures 9a and 9b, and particularly showing Figure 9a with handle 45. Support for the inclusion of handle 45 is provided by the original application, paragraph 71, indicated in the outstanding Office Action dated 2/1/05 and agreed to in the Examiner Interview of 2/10/05. Furthermore, substituted paragraph 71, provided elsewhere in this Amendment, has been amended to enter the inclusion of handle 45. The Office Action did not request a "marked up" copy of the amended drawing so no such copy has been provided.